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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/749,018	12/29/2003	Michael H. Wong	MERLYN-1/CIP-3	8426	
1054	7590 04/07/2006		EXAM	EXAMINER	
LEONARD TACHNER, A PROFESSIONAL LAW			MITCHELL,	MITCHELL, TEENA KAY	
<b></b>	CORPORATION 17961 SKY PARK CIRCLE, SUITE 38-E			PAPER NUMBER	
IRVINE, CA	•	3743			
			DATE MAILED: 04/07/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

U.S. Patent and Trademark Office PTOL-326 (Rev. 7-05)  Office A	ction Summary P	art of Paper No./Mail Date 03242006					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summar Paper No(s)/Mail [ 5) Notice of Informal 6) Other:						
Attachment(s)	∆ □ late=::	W/PTO 413)					
Gee the attached detailed Office action for a list of the certified copies not received.							
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
<ul> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>							
1. Certified copies of the priority documents have been received.							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
Priority under 35 U.S.C. § 119							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
9) The specification is objected to by the Examiner.							
Application Papers							
8) Claim(s) are subject to restriction and/or election requirement.							
7) ☐ Claim(s) is/are objected to.							
6)⊠ Claim(s) <u>1-21</u> is/are rejected.	5) Claim(s) is/are allowed. 6) Claim(s) 1-21 is/are rejected						
4a) Of the above claim(s) is/are withdrawn from consideration.							
4) Claim(s) <u>1-21</u> is/are pending in the application.							
Disposition of Claims							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
	1)⊠ Responsive to communication(s) filed on <u>09 January 2006</u> .  2a)□ This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
Status							
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If NO period for reply is specified above, the maximum statutory period v</li> <li>Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	n the mailing date of this communication. ED (35 U.S.C. § 133).					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.							
Period for Reply							
The MAILING DATE of this communication app	Teena Mitchell	3743					
Office Action Summary	Examiner	Art Unit					
	10/749,018	WONG ET AL.					
	Application No.	Applicant(s)					

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation of "...rod is shaped to permanently conform..." the specification as originally filed does not provide support for the rod to be shaped to permanently conform; such limitation would constitute new matter.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 8, 11-15, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Plzak (3,395,711).

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Plzak in an endotracheal tube (30) discloses: a stylet (16) comprising an elongated immaleable rod (Col. 3, lines 14-26; based on a standard dictionary definition of "rigid; Not bending: INFLEXIBLE." The stylet of Ptzak is readable upon the claimed limitation of immaleable) having a diameter that is less than the inner diameter of said tube and having a length that is shorter than said tube (Figs. 2, 5).

With respect to claim 2, Plzak discloses wherein said rod it shaped to permanently conform to the curvature of said tube (Figs. 2, 5).

With respect to claim 3, Plzak discloses a limiting device affixed to the proximal end of the said rod for engaging the proximal end of said tube to limit the insertion of said rod into said tube (18, 36).

With respect to claim 4, Plzak discloses wherein said limiting device (18, 36) is shaped for grasping by at least one finger of a human hand.

With respect to claim 5, Plzak discloses wherein said rod has a distal end having an enlargement (at 20).

With respect to claim 7, Plzak discloses wherein said rod has a bent distal end (20).

With respect to claim 8, Plzak discloses wherein the rod has a uniform straight shape over most of its length (Figs. 2, 5).

With respect to claim 11, Plzak discloses an endotracheal tube (30) having an articulable distal portion for manipulation during insertion into an airway, an immaleable stylet (16) for insertion into the tube to rigidize the tube along length not including the articulable distal portion; the stylet comprising: an elongated, shape-retaining, non-

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flexible rod having a diameter smaller than the inner diameter of said tube and having a length that is shorter than said tube (Figs. 2, 5).

With respect to claim 12, Plzak discloses wherein said rod is shaped to permanently conform to the curvature of said tube (Figs. 2, 5).

With respect to claim 13, Plzak discloses a limiting device affixed to the proximal end of the said rod for engaging the proximal end of said tube to limit the insertion of said rod into said tube (18, 36).

With respect to claim 14, Plzak discloses wherein said limiting device (18, 36) is shaped for grasping by at least one finger of a human hand.

With respect to claim 15, Plzak discloses wherein said rod has a distal end having an enlargement (at 20).

With respect to claim 17, Plzak discloses wherein said rod has a bent distal end tip (20).

With respect to claim 18, Plzak discloses wherein said rod has a uniform straight shape over most of its length (Figs. 2, 5).

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6, 10, 16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plzak (3,395,711).

With respect to claim 6, Plzak does not teach the rod having a distal end, which is flattened. At the time the invention was made, it would have been an obvious matter of design consideration to a person of ordinary skill in the art to have the rods distal end flattened because Applicant has not disclosed that having a flattened distal end of the rod provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the distal end of the rod being the same size as the proximal end. Therefore, it would have been an obvious matter of design consideration to modify Linder to obtain the invention as specified in claim 6

With respect to claim 10, Linder does not teach the rod made of biocompatible polymer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the rod of a biocompatible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. In re Leshin, 227 F.2d 197, 125 USPQ 416.

With respect to claim 16, note rejection of claim 6 above.

With respect to claim 20, note rejection of claim 10 above.

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Claims 9, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plzak (3,395,711) in view of Linder et.al. (3,957,055).

With respect to claim 9, Plzak does not teach the rod diameter which is in the range of 2 mm to 11 mm. However, Linder does teach that the guide may be made in a range of thicknesses and lengths appropriate for cooperation with all endotracheal catheters (Col. 1, lines 31-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the rod diameter in the range of 2mm to 11 mm based on the endotracheal catheter being used as taught by Linder.

With respect to claims 19 and 21, note rejection of claim 9 above.

### Response to Arguments

Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teena Mitchell Primary Examiner Art Unit 3743 March 24, 2006 Page 7

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